Remarks

Claims 1-45 are pending in the application.

§ 103 Rejection of Curtet in view of Kerč

Claims 1-45 remain rejected under 35 U.S.C. § 103 as being obvious over Curtet et al (U.S. Patent No. 4,895,726) in view of Kerč et al (U.S. Patent No. 6,042,847).

Applicants respectfully traverse the rejection and respectfully submit that neither Curtet nor Kerč disclose or suggest the claimed capsules having the claimed fenofibrate to polymer ratio of between 1:10 and 4:1 and containing a disintegrating agent. *See* independent claims 1, 11, 18, 25, 34 and 40.

The hydrophilic polymers in the present invention are used in addition to disintegrating agents. For example, polyvinylpyrrolidone (PVP) and cross-linked polyvinylpyrrolidone (X-PVP) are different materials exhibiting different properties. For example, in one embodiment, the invention uses PVP as the hydrophilic polymer and X-PVP as the disintegrating agent. The claimed invention used both a hydrophilic polymer and a disintegrating agent in the capsules of the invention.

Curtet fails to disclose the presence of both a hydrophilic polymer and a disintegrating agent, because Curtet uses only a cross-linked PVP (i.e., a disintegrating agent). One skilled in the art would recognize that Curtet's cross-linked PVP is not a hydrophilic polymer within the meaning of the invention because the specification of the present invention teaches that it is a disintegrating agent.

Assuming, *arguendo*, the cross-linked PVP used in Curtet is a polymer of the present invention (which it is not), the cited references still do not disclose or suggest the claimed weight ratios of fenofibrate to polymer of between 1:10 and 4:1.

Curtet provides working examples comprising 200 grams fenofibrate and 7 grams cross-linked polyvinylpyrrolidone,[1] such that the weight ratio of fenofibrate to cross-linked polyvinylpyrrolidone is 29:1. Neither Curtet nor Kerč provide any motivation or suggestion to drastically reduce the weight ratio of fenofibrate to cross-linked polyvinylpyrrolidone (PVP) of 29:1 in Curtet to fall within the claimed range of fenofibrate to polymer of between 1:10 and 4:1.

[1] Curtet at column 2, lines 30-40 and column 2, line 65 to column 3, line 5, assuming, *arguendo*, that cross-linked PVP is a hydrophilic polymer (which it is not).

The weight ratio in Curtet is significantly different than the claimed weight ratio and there is no motivation or suggestion in any of the references to arrive at the claimed weight ratio of between 1:10 and 4:1. The ratio of fenofibrate to polymer in Curtet has greater than 7 times more fenofibrate to cross-linked PVP than the claimed ratio of fenofibrate to polymer. There is simply no motivation in any of the references to drastically reduce the ratio used in Curtet to arrive at the claimed invention.

The PTO asserts that Applicants failed to show the criticality of the claimed ratio. Applicants respectfully disagree. Applicants noted the PTO's comments in the section "Response to Arguments" but note that the Blouquin Declaration[2] was not commented on by the Examiner.[3] The Bloquin Declaration shows, in addition to the data presented in the application,[4] the criticality of the claimed ratio.

Applicants respectfully submit that the PTO erred when stating:

> *"Admittedly, while the prior art teaches ratios of fenofibrate to polymer that are slightly different than that claimed, the Examiner points out that the differences in ratio do not impart a patentable distinction over the explicit reference teachings."*

The difference from the ratio in the prior art is not *"slightly different"* than the claimed ratio. The difference of the ratio in the prior art is significantly different than the claimed ratio. Assuming *arguendo* that X-PVP as used in Curtet is a hydrophilic polymer within the meaning of the invention (which it is not), the ratio used in Curtet is 29:1, which is at least 7 times the limit of the range of the invention. One would not refer to this as "*slightly different.*"

The inventors of the present claims did not discover an "optimum or workable ranges," of fenofibrate and hydrophilic polymer, but actually discovered an entirely different composition, where the use of a substantially higher amount of polymer affords suprabioavailability.

Applicants respectfully submit that Curtet does not disclose a composition comprising both a hydrophilic polymer and a disintegrating agent; and the Bloquin Declaration and examples demonstrate the criticality of the claimed ratio of fenofibrate to polymer.

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[2] duly listed in the IDS attached to the instant office action.
[3] *See* the response dated January 26, 2007 at page 3, last paragraph and page 3.
[4] *See* the response dated January 26, 2007 at page 3, second and third full paragraphs.

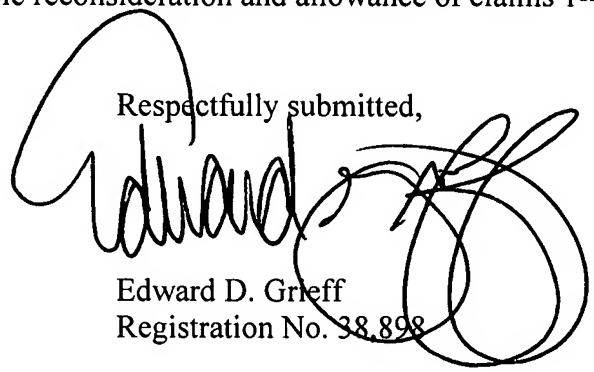
Kerč does not cure the deficiencies of Curtet. Kerč does not provide any motivation or suggestion to modify the weight ratios of the components in Curtet to arrive at the claimed weight ratios.[5] This is particularly the case since Curtet teaches relatively fast release fenofibrate compositions when compared to the sustained release compositions described by Kerč.

Kerč teaches away from the claimed invention because Kerč teaches a three-phase pharmaceutical formulation with controlled release properties. If Curtet and Kerč were combined, one skilled in the art would be motivated to produce a formulation having controlled or extended release properties by varying the weight ratio of fenofibrate:polymer to produce, i.e., a dissolution profile that is significantly slower than the dissolution profile of the invention. One skilled in the art would not combine these references because Kerč's proposed modification (i.e., extended release) would change the principle of operation of Curtet's composition (i.e., relatively faster release than Kerč). *See* MPEP at 2143.02.

In view of the above, Applicants respectfully submit that the presently claimed invention is unobvious over Curtet in view of Kerč and respectfully request that the rejections under § 103 be withdrawn.

An early and favorable reconsideration and allowance of claims 1-45 is respectfully requested.

Respectfully submitted,



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[5] Applicants respectfully submit that Kerč does not provide motivation to specifically choose fenofibrate from among the compounds disclosed therein because Kerč only provides working examples that use nifedipine or nicardipine.